SH

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OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 51-F-0021

Customer Number: 728

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

Us Army Med Research Inst Of Infectious Disease
Veterinary Medicine Division
1425 Porter St
Frederick, MD 21702

NOV 27 2009

Telephone: (301) 619 4708

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)*

FACILITY LOCATIONS *(Sites)* *See Attached Listing*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	266	150	614	621	1385
7. Hamsters	0	96	651	321	1068
8. Rabbits	0	124	121	200	445
9. Non-human Primates	216	159	271	191	621
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Horses	0	4	0	0	4
13. Other Animals					
Goats	0	45	0	0	45

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)c

DATE SIGNED
23 NOV 09

EB 12-4-09

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

NOV 2 7 2009

2. **Number** 621 **of animals used in this study.**

3. **Species (common name)** Guinea Pigs **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

Guinea pigs used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)

Agency N/A **CFR** N/A

Optional Column E Explanation Form

NOV 2 7 2003

1. **Registration Number:** 51-F-021 / 728

2. **Number** 321 **of animals used in this study.**

3. **Species (common name)** Hamsters **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Hamsters used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)**

Agency N/A **CFR** N/A

Optional Column E Explanation Form

NOV 2 7 2003

1. **Registration Number:** 51-F-021 / 728

2. **Number** 200 **of animals used in this study.**

3. **Species (common name)** Rabbits **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Rabbits used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)

Agency N/A **CFR** N/A

Optional Column E Explanation Form

NOV 2 7 2009

1. **Registration Number:** 51-F-021 / 728

2. **Number** 191 **of animals used in this study.**

3. **Species (common name)** Non-human Primates **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Nonhuman primates used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)**

Agency N/A **CFR** N/A